GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:4187
ANSWERED ON:11.08.2017
Tuberculosis Drugs
Kothapalli Smt. Geetha

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the WHO has suspended the approval of tuberculosis drugs made by India's Svizera Labs, a major supplier to developing countries;

(b) if so, the details thereof and the reasons therefor;

(c) whether the Government is considering to permit independent experts to retest batches of medicine available in the market and to recall supplies depending on the outcome of those test; and

(d) if so, the details thereof and if not the reasons therefor?

Answer

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI FAGGAN SINGH KULASTE)
(a) & (b): WHO had informed Central Drugs Standard Control Organisation (CDSCO) that a notice of concern was issued on 11.09.2015 to M/s. Svizera Labs Pvt. Ltd., Mumbai for supply of prequalified products under its scheme, based on inspection of the firm by the WHO Prequalification team wherein several critical and major deviations from WHO GMP standards were revealed. However, as per information available on WHO website at present, WHO has issued a corrigendum mentioning that notice to M/s. Svizera was published due to an administrative error and was, therefore, removed from the WHO website.
(c) & (d): The manufacture, sale and distribution of drugs in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 thereunder through a system of licensing and inspection. Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments. SLAs are legally empowered to take stringent action against violation of provision of the Act and Rules including product recall.
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